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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

February 22, 2002

**WARNING LETTER**
**CHI-16-02**

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Mr. Victor L. Shriver III
2003 Highway 96 N
Ursa, IL 62376

Dear Mr. Shriver:

An investigation of your dairy operation conducted February 8 – 11, 2002, found that cattle from your establishment were offered for sale for slaughter as human food in violation of Section 402(a)(2)(C)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act).

On or about October 30, 2001, you sold cattle for slaughter as human food to [redacted], [redacted]. USDA analysis of tissue samples collected from the animals identified the presence of 3.35 and 3.16 parts per million (ppm) Gentamicin in the kidney tissues. There is no established tolerance for Gentamicin in cattle (Title 21, Code of Federal Regulations, Part 556.300). The presence of this drug in the edible tissue from the animals causes the food to be adulterated under the Act.

You are adulterating the drug, Gentamicin OTC, that your farm uses on cattle within the meaning of Section 501(a)(5) when you fail to use the drug in conformance with its approved labeling. Your use of the drug for E. coli mastitis, a condition not specified in its labeling, causes the drug to be unsafe for use.

Our investigation also found that you lack an adequate system for assuring that animals medicated by you have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues from edible tissue. You need to implement a system in which to record and maintain permanent drug treatment records that will adequately identify and/or segregate drug treated animals.

The above is not intended as an all-inclusive list of violations. As a producer of animals offered for human consumption, you are responsible for assuring that your overall operation and the food products you produce for distribution are in compliance with the law.

You should take prompt action to correct the violations, and you should establish procedures whereby such violations do not recur. Failure to promptly correct the violation may result in regulatory action without further notice, such as seizure and/or injunction. This letter constitutes notification under the law.

Please advise this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include each step that has been taken or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your response should be directed to Richard Harrison, Director, Compliance Branch.

Sincerely,

\s\
W. Charles Becoat
Acting District Director